IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF **PUBLIC VERSION**

WYETH'S ANSWERING MARKMAN BRIEF

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19801
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Barbara R. Rudolph
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

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I. PRELIMINARY STATEMENT

Contrary to the implication in Impax's Opening Markman Brief, it was not the intent of the Hatch-Waxman Act to penalize pharmaceutical companies that spend billions of dollars in research and development to bring new drug products and methods of treatment to the market. Nor was it the Act's intent to reward copyists like Impax who ignore legitimate patent rights that protect the fruits of that research and development. Make no mistake. Impax is not a white knight on a quest to protect the public from high drug prices. Rather, Impax is motivated by money, and it pursues a business strategy of copying successful drugs so that it can avoid the expense and risk of developing its own innovative products.

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Impax alleges that Wyeth developed Effexor XR because it was "[c]oncerned that its monopoly on venlafaxine was coming to an end." [Impax Br., D.I. 162, at 1].

Thus, this is not a case where Wyeth has reformulated a successful product and obtained a patent to preserve its market position. Rather, this is a case where Wyeth made an important advance many years ago, and the success of its product is directly tied to that advance, which is the subject of the patents-in-suit.

Impax also alleges that Wyeth has made "billions of dollars in sales of venlafaxine under the brand name Effexor." [Impax Br., D.I. 162, at 1]. But that commercial success results from the extended release formulation of Effexor XR, not venlafaxine alone. Had Impax simply

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[1] Unless otherwise indicated, citations to exhibits refer to the exhibits in the Declaration of Karen Jacobs Louden in Support of Wyeth's Opening Markman Brief [D.I. 166] and in the Declaration of Karen Jacobs Louden in Support of Wyeth's Answering Markman Brief.

sought to market immediate release venlafaxine, and not the invention disclosed and claimed in the patents-in-suit, then this lawsuit would be unnecessary. The patents-in-suit do not cover Effexor, Wyeth's immediate release venlafaxine product, and Wyeth has never suggested otherwise. Impax is free to market a generic version of Wyeth's immediate release Effexor upon the June 2008 expiration of the basic patent on venlafaxine.

But Impax is not prepared to put its money where its mouth is. Impax does not want to sell a generic version of immediate release Effexor because that product suffers from adverse side effects, particularly nausea and vomiting, and sales have been modest -- less than a tenth of Effexor XR's annual sales. Rather, Impax wants to piggyback on Wyeth's innovation and clinical research so that it can sell a generic copy of Wyeth's extended release version of venlafaxine, Effexor XR. That decision by Impax speaks volumes about the innovations claimed in Wyeth's patents and the lack of merit of Impax's attacks on those patents.

II. WYETH, NOT IMPAX OR OTHERS, PAVED THE WAY FOR THE DEVELOPMENT OF EXTENDED RELEASE FORMULATIONS OF VENLAFAXINE

In its Background discussion, Impax seeks to downplay Wyeth's development efforts on extended release formulations of venlafaxine, even suggesting that it was expected that an extended release formulation would be clinically effective in humans. [Impax Br., D.I. 162, at 3].[2] Nothing could be further from the truth.

The Wyeth inventors initially experimented with conventional hydrogel tablet technology, but they were not able to slow the release rate of venlafaxine sufficiently to meet their desired bench test release profile (*in vitro* dissolution tests). Subsequently, the Wyeth inventors succeeded in developing prototype formulations with laboratory release rates that justified proceeding to tests in humans. As

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discussed in Wyeth's Opening Brief at 4-5, however, it could not be predicted whether these, or any other extended release formulations of venlafaxine, would be clinically effective or tolerable. For example, prior to the human testing Wyeth conducted, it could not be predicted whether venlafaxine would be sufficiently absorbed, if at all, from the lower intestines, where venlafaxine necessarily would be released from the extended release formulation. This unpredictability is recognized in a leading biopharmaceutics textbook:

> A factor that circumscribes the use of oral prolonged-release medication is the limited residence time of the dosage form in the small intestine. Absorption from the colon may be poor or unpredictable. Hence, small intestine transit time is often of paramount importance in determining the bioavailability of the drug from this dosage form.

[Ex. 22 at 134]. And another leading pharmacokinetics textbook instructs that *in vivo* testing is the only recourse:

> But clearly, whenever release of drug beyond the stomach continues for 4 hr [sic, hours] or more, some of the drug is likely to be released in the large intestine . . . . More needs to be known about the relationship between the physiochemical properties of a molecule and intestinal permeability. Currently, the only recourse is to evaluate the drug delivery system *in vivo*.

[Ex. 23 at 133]. Consistent with the unpredictable nature of the problem,

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, culminating in the filing of the NDA for Effexor XR with the FDA in May 1996.

Impax argues that Wyeth's patent specification is filled with "failed experiments," and contends that it provides no teachings to others on how to make formulations other than those "comprising venlafaxine, MCC, and, optionally, HPMC." [Impax Br., D.I. 162, at 3-4]. But what Impax refers to as "failed experiments" reflects nothing more than a heat buildup problem with a certain type of extruder that made shaping the extruded material into spheroids "difficult." [Ex. 1, col. 5, ll. 1-13 and col. 6, ll. 6-11]. The patent continues, stating that HPMC made the shaping of spheroids "practical" when MCC was being extruded in that extruder. *Id.* The patent also states, however, that when MCC is extruded in larger-scale extruders, heat buildup was not a

problem such that shaping of the spheroids was practical even without HPMC. [Ex. 1, col. 6, ll. 5-11]. One skilled in the art would clearly recognize that whatever "difficulty" was involved in connection with extrusion was equipment specific, and is alleviated with different extruders. [Ex. 24 at ¶ 16].

Moreover, Impax ignores that the patent provides an *in vitro* dissolution profile bench test to help screen for other formulations that would likely meet the claimed pharmacokinetic and therapeutic properties. [Ex. 1, col. 6, ll. 41-64 (Table 1)].

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Impax argues that Synthon successfully developed a hydrogel tablet form of venlafaxine. [Impax Br., D.I. 162, at 6]. A review of the Synthon patent Impax cites reveals that Synthon also utilized the *in vitro* dissolution data from Table 1 of Wyeth's patents to develop its formulations. [Impax Ex. M, col. 8, ll. 7-20].

The Wyeth patents disclose as a preferred procedure for making the venlafaxine-containing core mixing venlafaxine, water, and microcrystalline cellulose (a diluent and binder), and then extruding and spheronizing the mixture.

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Citing to a 1984 study, Impax argues that it is impossible to use the extrusion and spheronization process with any pharmaceutical excipient other than microcrystalline cellulose. [Impax Br., D.I. 162, at 6-7]. Aside from being irrelevant to the state of the art as of 1996, the effective filing date of Wyeth's patents [Ex. 24 at ¶ 20], the article Impax cites does not support this proposition. The study referred to in the article was very limited, investigating only four excipients other than microcrystalline cellulose compounds, and used only water as the granulating fluid. [Ex. 24 at ¶ 21 and Ex. C at 80-87]. Others using different excipients were able to use the extrusion and spheronization process using excipients other than microcrystalline cellulose. [Ex. 24 at ¶ 22 and Exs. D and E].

Although Impax correctly notes that Wyeth's patents do not recite a list of various known technologies for making extended release formulations, a patent applicant need not describe

every conceivable way of practicing the claimed invention, and it certainly is not required to describe what is already known to those skilled in the art. (*See* Section IV(A)(1) below). Wyeth disclosed a preferred procedure for making its extended release formulations, and provided an extremely helpful bench test to screen for other formulations that would likely achieve the therapeutic benefits of its invention. Wyeth broadly claimed methods that utilize extended release formulations that achieve specific pharmacokinetic properties, namely, peak blood plasma levels of venlafaxine within a specified time period or within a specified concentration, and that are therapeutically effective. Impax has a problem with these claims because it literally infringes them as written. But the claims as written are patentable over the prior art and are supported by an enabling disclosure. Thus, there is no legitimate basis for Impax to ask the Court to rewrite the claims.

III. THE MARKMAN RULING IN THE TEVA CASE WAS VACATED AND IS OF NO LEGAL EFFECT

Impax alleges that the Markman ruling in the Teva case is entitled to "substantial deference, if not outright preclusive effect." [Impax Br., D.I. 162, at 9]. That ruling, however, does not give rise to collateral estoppel because no final judgment was entered in the case; that ruling has no precedential effect because the court vacated its Markman decision after the settlement; and that ruling has no persuasive value because the opinion itself reveals an analysis flawed in several critical respects.

The Markman ruling in the Teva case does not give rise to collateral estoppel because no final judgment issued, and no appeal was ever available. Indeed, the case settled before the court ever ruled on infringement or validity. The Federal Circuit has long held that "judicial statements regarding the scope of patent claims are entitled to collateral estoppel effect in a subsequent infringement suit only to the extent that determination of scope was essential to a final judgment on the question of validity or infringement." *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 704 (Fed. Cir. 1983). As cautioned in *A.B. Dick*, "[e]xcept in the context of validity or infringement, judicial statements regarding the scope of patent claims are hypothetical

insofar as they purport to resolve the question of whether prior art or products not before the court would, respectively, anticipate or infringe the patent claims." *Id.* (emphasis added). The wisdom of that caution is borne out in actual cases, where judges often amend claim constructions during the course of a litigation or in a subsequent litigation. For example, in *KX Industries, L.P. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2d 380, 387-89 (D. Del. 2000), Judge McKelvie had previously construed the claims of the patent in another litigation but adopted a different construction in the subsequent litigation, explaining that his "earlier opinion in [the previous litigation] about the scope of [Plaintiff's] disclaimer was wrong." And in the Teva case, Judge Martini never decided infringement or validity.

Impax argues that Wyeth should have appealed Judge Martini's incorrect claim construction ruling by "stipulat[ing] to a judgment of non-infringement" and appealing to the Federal Circuit. [Impax Br., D.I. 162, at 2]. Wyeth did not enter into such a stipulation because Teva was infringing Wyeth's patents, even under Judge Martini's incorrect claim construction. At the time the Teva case was settled, cross motions for summary judgment on infringement under the doctrine of equivalents had been briefed, argued, and were pending. Moreover, contrary to Impax's suggestion, settlements of litigation are not against the public interest, and certainly are not improper. Nor was it improper for Judge Martini to vacate his Markman ruling.

Furthermore, the Markman ruling in the Teva case has no precedential effect because it was vacated. *See Marshall v. Whittaker Corp.*, 610 F.2d 1141, 1145 (3d Cir. 1979). Impax argues that the vacatur should be ignored because the parties, with Judge Martini's complicity, allegedly vacated the Markman decision for improper reasons. Impax cites no evidence or legal authority for this proposition, however. Impax's contention that Wyeth is engaged in forum shopping [Impax Br., D.I. 162, at 1, 9] also is without merit. The claim construction issues addressed by Judge Martini and presented to this Court are issues of law that ultimately will be decided by the Federal Circuit, regardless of the district court from which an appeal is taken. Wyeth, moreover, is entitled to sue Impax in Delaware, its corporate home.

Finally, the Markman ruling in the Teva case has no persuasive value because the Court's reasoning was flawed in several critical respects. As explained in detail in Wyeth's Opening Brief, Judge Martini discounted the claims themselves, gave no effect to the doctrine of claim differentiation, misinterpreted the specification, and ignored the prosecution history. [*See* Wyeth Br., D.I. 166, at 17, 21-24, 27].

The cases Impax cites do not support its argument that the vacated decision be given either deference or preclusive effect. [Impax Br., D.I. 162, at 9]. For example, in *KX Indus.*, Judge McKelvie "specifically refuted" the theory that the goals of judicial uniformity are best followed by applying previous claim constructions. In *Texas Instruments, Inc. v. Linear Technologies Corp.*, 182 F. Supp. 2d 580, 588-89 (E.D. Tex. 2002), the court granted the defendant's motion for a Markman hearing after finding "no authority, either binding or persuasive, that instructs that it must utilize the claim construction reached by the court in the [previous] Litigation." *Id.* at 589-90. In *Abbott Laboratories v. Dey, L.P.*, 110 F. Supp. 2d 667, 669-71 (N.D. Ill. 2000), the prior action was tried and appealed, unlike the Teva case where no decision was reached on infringement or validity. And in *TM Patents, L.P. v. IBM Corp.*, 72 F. Supp. 2d 370, 378 (S.D.N.Y. 1999), the court expressly noted that the Markman rulings in question "were not vacated as part of the settlement . . . ." In fact, Impax has failed to cite any case where a vacated Markman ruling was given any effect.

A more analogous case is *Kollmorgen Corp. v. Yaskawa Electric Corp.*, 147 F. Supp. 2d 464 (W.D. Va. 2001), *dismissed*, 33 Fed. Appx. 496 (Fed. Cir. 2002), where the court denied the accused infringer's motion to apply offensive collateral estoppel and adopt a claim construction rendered in a first action that was settled before infringement or validity were decided. The *Kollmorgen* court correctly recognized that "a consensual settlement between the parties does not constitute 'a final judgment.'" It went on to explain:

> [T]his Court strongly believes that a party should have an opportunity to appeal a potentially preclusive order. Defendants . . . seem to ignore the reality that the Federal Circuit consistently refuses to review lower court's patent claim constructions on interlocutory appeal . . . .

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> . . .[T]he lack of any realistic opportunity for Federal Circuit review greatly outweighs the adequacy of the hearing and the nature of the *Markman* Order. . . .As the Wisconsin Court never reached a decision as to the patent infringement claim, the order necessarily could not prove essential to an non-existent final judgment, and thus, collateral estoppel will not apply . . . .
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> Courts need not blindly apply the doctrine of collateral estoppel to a prior *Markman* ruling that construes a patent's scope and claim. The Federal Circuit's review of a lower court's ruling is crucial to providing the public with a uniform and proper patent claim construction.

Id. at 468-470 (citations omitted). *See also Lectrolarm Custom Services, Inc. v. Vicon Indus., Inc.*, No. 03-2330, 2005 WL 2177000, at *3 (W.D. Tenn. Sept. 2, 2005) (refusing to give preclusive effect to a prior claim construction where the case settled prior to appellate review of the Markman decision, explaining: "Consequently, the [prior] decision has no stare decisis effect on this court. Because the [prior] decision was not reviewed by the Federal Circuit, it cannot be viewed as a final order for the purposes of collateral estoppel.").

For the foregoing reasons, the Markman ruling in the Teva case is entitled to no weight here.

IV. THE CLAIM TERMS AT ISSUE

A. Extended Release Formulation

Impax's Brief ignores a critical aspect of the claim construction analysis, the claims themselves. To the extent Impax focuses on the specification, it cherry picks portions out of context in an effort to create a definition for "extended release formulation" that bears no resemblance to the ordinary and customary meaning of that term. Facing a prosecution history that telegraphs loud and clear that "extended release formulation" is not restricted to a set of inactive ingredients, it seeks to manufacture a bar where none exists to avoid that inescapable conclusion.

1. Impax's Attempt To Narrowly Construe "What The Inventors Invented" Relegates The Claims To A Passive Subsidiary Role And Ignores Most Of The Specification

Although Impax's Brief is entitled "Opening Claim Construction Brief" (emphasis added), conspicuously absent is a discussion of the claims themselves. That is because the claims cannot be reconciled with Impax's proposed construction. In essence, Impax asks the Court to ignore the claims, look to the specification and assess "what the inventors invented," and use that assessment to redraft Wyeth's method claims to require a litany of specific ingredients. That argument is fatally flawed in two respects. First, it violates the rule that the claims define the invention. And second, when Impax looks to the specification to define "what the inventors invented," it ignores the "use aspect of the invention," it ignores the specification as a whole, including the value of the dissolution profile as a screening tool, and it seeks to create a special definition for "extended release formulation" where none exists in the specification.

Although recent Federal Circuit opinions emphasize the importance of the specification when construing claims, it remains "a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). This principle has been accepted, affirmed, and reaffirmed by the Supreme Court for more than a century. *See, e.g., Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("The claim 'defines the scope of a patent grant.'"); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant."); *Altoona Publix Theatres v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute, it is the claims of the patent which define the invention."); *Smith v. Snow*, 294 U.S. 1, 11 (1935) ("[T]he claims of the patent, not its specifications, measure the invention."); *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("[The statutorily required] distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely

what it is that is patented to the appellant in this case."). Nothing is more fundamental to patent law than this principle.

Here, the claims could not be clearer. Because some claims recite "extended release formulations" with inactive ingredient limitations, and other claims recite "extended release formulations" without inactive ingredient limitations (but with other pharmacokinetic limitations), the only reasonable interpretation of the latter is that those claims do not require formulations with a specific set of inactive ingredients. Impax is silent on this glaring difference between the claims. Added to that logic are the facts that (1) the asserted method claims recite one ingredient (venlafaxine hydrochloride), which suggests that the formulations are not limited to other specific ingredients, another fact Impax ignores and (2) dependent claims recite specific inactive ingredients, which would make those limitations redundant if the term "extended release formulation" already included those ingredients, a fact Impax admits (Impax Br., D.I. 162, at 15).[3]

As the Federal Circuit reiterated as recently as today in *Honeywell International Inc. v. Universal Avionics Systems Corp.*, Nos. 05-1112, -1151, -1152, slip op. at 14 (Fed. Cir. May 25, 2007), "the claim itself provides considerable information about its meaning." *Honeywell* is attached as Ex. A hereto. In *Honeywell*, since the claim identified what the term "alert envelope" encompasses, the court concluded that "one of skill in this art would agree that the claim defines this term adequately without additional limitations." Slip op. at 14. So too here. Since the method claims expressly recite that "said [extended release] formulation contains venlafaxine hydrochloride as the active ingredient," one skilled in the art would understand that "additional" ingredients regarding "extended release formulation" are not part of the claim.

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[3] Impax cites to claim 21 of the '171 patent, and argues that Wyeth's proposed claim construction likewise leads to redundancy. [Impax Br., D.I. 162, at 15]. Impax is wrong. The reference to "venlafaxine hydrochloride" in the preamble of claim 21 is in reference to the "plural daily doses" employed with the immediate release formulation. The subsequent reference to venlafaxine hydrochloride in the body of claim 21 is in reference to the extended release formulation. There is no redundancy.

Unable to address the difference between the claims, Impax ignores them, arguing that "[t]he doctrine of claim differentiation is only a guide; it is 'not a hard and fast rule of construction.'" [Impax Br., D.I. 162, at 15]. But as the Federal Circuit reiterated today in *Honeywell*, when a dependent claim includes a limitation, that is "**strong evidence against limiting**" the independent claim to require that limitation. Slip op. at 15 (emphasis added).

Moreover, even the case Impax cites for its contention that claim differentiation should not be applied, *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182 (Fed. Cir. 1998), relied heavily on claim differentiation to reject the accused infringer's attempt to narrowly construe a disputed term. Indeed, *Comark* states the doctrine of claim differentiation creates a "significant" presumption that each claim in a patent has a different scope. *Id.* at 1187. *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 (Fed. Cir. 1988), which Impax also cites, is distinguishable because the claim differentiation argument was based on two very different independent claims, and the claim term being construed was a "means-plus-function" limitation that is statutorily limited to the means disclosed in the specification and their equivalents. *Id.* at 1478-80. Here, by contrast, Impax's proposed claim construction renders a dependent claim superfluous.

Beyond ignoring the claims, Impax ignores most of the specification when it characterizes "what the [Wyeth] inventors invented." Impax starts off its discussion of "The Patents in Suit and their Prosecution History" by citing a cropped quote from the Abstract - "**the invention** comprises an extended release formulation of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, [MCC] and, optionally, [HPMC] coated with a mixture of ethyl cellulose and [HPMC]." [Impax Br., D.I. 162, at 4 (emphasis in Impax Brief)]. But in its entirety the Abstract reads (emphasis added):

> This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better control of blood plasma levels than conventional tablet formulations which must be administered two or more times a day and further provides a lower incidence of nausea and vomiting than the conventional tablets. ***More particularly***, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising

> a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

Thus, at the very outset, the patent specification defines the invention broadly, and makes clear that the formulation with specific inactive ingredients is a preferred example for practicing the invention.

What the inventors invented included a therapeutic method that is not limited to a specific extended release formulation. The Brief Description of the Invention describes this "use aspect of this invention" in terms of blood plasma levels of venlafaxine, not in terms of a specific extended release formulation. That "use aspect" of the invention included the discovery that venlafaxine formulations that produce those pharmacokinetic profiles can be administered once a day. [Ex. 1, col. 2, ll. 14-45]. The "use aspect" of the invention also included the discovery that formulations that produce those pharmacokinetic profiles will reduce the incidence of nausea and emesis as compared to the immediate release form of venlafaxine, resulting in better tolerance and better efficacy. [Ex. 1, col. 2, ll. 46-62]. Those discoveries were not dependent on a specific extended release formulation with a defined set of ingredients. It is this "use aspect of the invention" that is claimed in the asserted method claims. Impax's Brief does not even mention the "use aspect" of the invention described in the specification.

Impax also attempts to narrowly circumscribe Wyeth's invention and contribution to the field by focusing on a paragraph from the Brief Description of the Invention that describes "the formulations of this invention." [Impax Br., D.I. 162, at 4]. Reading the Brief Description of the Invention in its entirety reveals that it is organized by scope, beginning with the broadest statement of the invention and progressively describing narrower inventions. The first paragraph describes the invention as "an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug [] component, which provides in a single dose, a therapeutic blood serum level over a twenty four hour period." [Ex. 1, col. 2, ll. 14-18]. The next two paragraphs describe "the use aspect of the invention" in somewhat narrower terms, providing specifics as "the therapeutic blood serum level." [Ex. 1, col. 2, ll. 20-62]. The next

paragraph is the paragraph cited by Impax. [Ex. 1, col. 2, l. 63-col. 3, l. 5.]. And the remaining paragraphs in the Brief Description of the Invention describe the formulations in progressively narrower terms. [Ex. 1, col. 3, ll. 6-63]. Thus, viewed in context, the paragraph that Impax cites is not "what the inventors invented," but only one aspect of the invention. The paragraph cited by Impax describes a preferred embodiment of the formulation aspect of the invention, which relate to the product claims. The method claims, in contrast, claim the "use aspect of the invention." They are not limited to the formulations that comprise the "formulations of this invention."[4]

Impax also contends that the "Detailed Description of the Invention" further describes "'**the extended release formulations of this invention**' as comprised of venlafaxine 'in admixture with [MCC] and [HPMC].'" [Impax Br., D.I. 162, at 4 (emphasis in Impax's Brief); Ex. 1, col. 4, ll. 9-12]. Impax asserts that this sentence constitutes a special definition of "extended release formulation." But this supposed special definition differs from another supposed special definition Impax points to in the "Brief Description of the Invention," because it does not mention the ingredients in the coating or the use of spheroids. [Impax Br., D.I. 162 at 4; Ex. 1, col. 2, l. 63 to col. 3, l. 2]. And Impax's proposed construction differs from both of these supposed special definitions in the patent's specification. Further, Impax simply ignores the specification's use of the term "extended release drug formulations" in the discussion of prior art [Ex. 1, col. 1, ll. 13-15], which supports the conclusion that the specification does not provide a special definition for "extended release formulation." The problem for Impax is that there is no special definition for "extended release formulation" in the Wyeth specification. Impax's efforts to piece together a definition on the fly evidences this fact.

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[4] Impax argues that since the inventors used the term "formulation," that implies that "the invention has specific ingredients." [Impax Br., D.I. 162, at 12]. But the term "extended release formulation" contains the same word, and even Impax admits that the ordinary meaning of "extended release formulation" is not limited to specific ingredients.

Impax further argues that the claims should be limited to the specific successful formulations disclosed in the specification because the specification reports other formulations that failed. As examples, Impax points to the specification's description of failed experiments using hydrogel technology and "a series of 'failed experiments' in making spheroids using an extrusion and spheronization process." [Impax Br., D.I. 162, at 3]. Here again, Impax fails to read the specification in its entirety.

The specification in the issued patent includes disclosures from two applications. In the application as originally filed, Wyeth reported experiments using an Alexanderwerk extruder:

> Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and hydroxypropylmethylcellulose [HPMC], different ratios of venlafaxine hydrochloride and filler, different binders such as polyvinylpyrrolidone [PVP], methylcellulose, water, and polyethylene glycol of different molecular weight ranges in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

[Ex. 1, col. 5, ll. 1-13]. Wyeth also conducted experiments with larger scale extruders using microcrystalline cellulose without HPMC to make the core. Wyeth filed a continuation-in-part application in which it added the following disclosure to the application:

> In the foregoing failed experiments and in Examples 1-4 [which added HPMC to the venlafaxine-microcrystalline cellulose mix], the extrusion was carried out on an Alexanderwerk extruder. Subsequent experiments carried out on Hutt and Nica extruders surprisingly demonstrated that acceptable, and even improved, spheroids could be made without the use of an hydroxypropylmethylcellulose.

[Ex. 1, col. 6, ll. 6-11]. In other words, the specification indicates that various excipients were used in an Alexanderwerk extruder, that heat buildup dried the microcrystalline cellulose extruded in an Alexanderwerk extruder such that it was "difficult" to shape the material into spheroids, that the addition of HPMC to the microcrystalline cellulose "made production of spheroids practical," and that microcrystalline cellulose could be shaped into spheroids without difficulty, even without the use of HPMC, when larger-scale Hutt or Nica extruders were used.

One skilled in the art would understand from reading the entire specification that when the larger extruders are used, excipients in addition to MCC could be extruded and spheronized. [Ex. 24 at ¶¶ 16, 23-24].

Thus, for Impax to characterize the specification as disclosing "a series of 'failed experiments' in making spheroids using an extrusion and spheronization process" is not correct. Moreover, the passages quoted above rebut Impax's argument that "the specification's repeated reference to the 'optional[]' inclusion of HPMC shows that the other ingredients — venlafaxine hydrochloride and MCC — are not optional." [Impax Br., D.I. 162, at 13]. As these passages show, the reference to HPMC as "optional" simply meant that when microcrystalline cellulose is used to make an extruded core, HPMC is an optional ingredient.[5] [*See also* Ex. 24 at ¶¶ 5-9].

Impax also argues that there were many known technologies for preparing extended release formulations (when Wyeth filed its patent applications. It further asserts that because Wyeth did not include a list of all these known technologies in its patents, Wyeth's claims must now be rewritten to exclude them. [Impax Br., D.I. 162, at 13-14]. Impax's argument is based on an incorrect premise--that patent specifications must include what those skilled in the art already know. As the court stated in *Koito Manufacturing Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004):

> This Court has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 664 (Fed. Cir. 1986); *In re Howarth*, 654 F.2d 103, 105 (CCPA 1981) ("An inventor need not, however, explain every detail since he is speaking to those skilled in the art."); *In re Lange*, 644 F.2d 856, 863 (CCPA 1981).

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[5] Impax's argument that the specification's disclosure of alternatives to HPMC evidences that the "inventive concept" is limited to a specific set of ingredients is a non-sequitor. [Impax Br., D.I. 162, at 13]. This disclosure does nothing more than provide additional information on the preferred embodiment.

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Accord Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art.") (citation omitted).

Moreover, Impax's argument also ignores the specification's disclosure that the "encapsulated formulations of this invention may be produced . . . by techniques understood in the art." [Ex. 1, col. 5, ll. 14-17] (emphasis added), and that the "following examples are presented to illustrate applicant's solution to the problem of preparation of the extended release drug containing formulations of this invention. [Ex. 1, col. 5, ll. 29-31] (emphasis added). These passages signal to those skilled in the art what they already know, namely, that there are other known techniques that could be used to make the "formulations of this invention." [Ex. 24 at ¶ 8].

Thus, that the Wyeth patents did not recite a litany of alternative known procedures for making extended release formulations is not surprising or unusual. [Ex. 24 at ¶ 13]. What is disclosed is the screening tool of Table 1 to hone in on other formulations to practice Wyeth's invention using various technologies already known to those skilled in the art.

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Having ignored significant portions of Wyeth's patent specification, Impax cites several cases [Impax Br., D.I. 162, at 10-12] to support its argument that the ordinary meaning of "extended release formulation" should be jettisoned in favor of an artificial definition that limits the term to Wyeth's preferred embodiment. None of those cases is analogous to this case, however, where the patent discloses a therapeutic method, formulations to practice that method, and a screen to identify other formulations that can be used in the method.

In *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350 (Fed. Cir. 2006), *Astrazeneca AB v. Mutual Pharmaceutical Co.*, 384 F.3d 1333 (Fed. Cir. 2004), and *Scimed Life*

Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed. Cir. 2001), the patent owner sought claim constructions that encompassed the very subject matter that had been expressly disclaimed or criticized in the specification. Here, Wyeth's proposed claim construction does not encompass such subject matter. Wyeth has explicitly excluded conventional hydrogel tablets from its proposed construction.[6]

Honeywell International, Inc. v. ITT Industries, Inc., 452 F.3d 1312 (Fed. Cir. 2006), is a *sui generis* case where it appears that the patent owner tried to redefine its invention after the fact by amending the title to the application and submitting self-serving statements to the PTO. The specification was replete with statements, including the introductory sentence in the specification, that "this invention relates to a fuel filter," and yet the patent owner obtained claims covering any "fuel injection system component." Under these unique circumstances, the court construed the claims to be limited to "fuel filters." *Id.* at 1318-19.

Here, the specification is not so limited. For example, the introductory sentence in the Brief Description of the Invention reads:

> In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug [] component, which provides in a single dose, a therapeutic blood serum level over a twenty four hour period.

[Ex. 1, col. 2, ll. 15-19]. This statement is not limited to a specific extended release formulation or specific set of ingredients. Thereafter, the specification discusses the "use aspect of the invention," which again is not limited to a specific extended release formulation or a specific set

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[6] Impax cites *Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258 (Fed. Cir. 2001), for the proposition that a patentee may define a term by implication by using it "throughout the entire patent specification, in a manner consistent with only a single meaning." [Impax Br., D.I. 162, at 12]. However, here, for example, Wyeth's inventors used the term "extended release formulation" in the Background of the Invention to describe certain prior art, and in the first sentence of the Brief Description of the Invention without any limitation to a specific formulation. Thus, contrary to Impax's argument, this is not a case where the term "extended release formulation" has been used throughout the specification in a manner consistent with Impax's proposed construction.

of ingredients. Thus, unlike *Honeywell*, the broad descriptions of the invention do not include the limitations that Impax seeks to import into the claims.

Impax next cites several cases to support its argument that, by using the word "invention" when describing "the formulations of this invention," Wyeth necessarily limited its method claims to methods using the specific formulations and specific ingredients described. *See Watts v. XL Sys., Inc.*, 232 F.3d 877 (Fed. Cir. 2000); *Alloc, Inc. v. ITC*, 342 F.3d 1361 (Fed. Cir. 2003); *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340 (Fed. Cir. 2004). In these cases, the Federal Circuit relied on statements in the specification that restricted the nature of the "invention" as a factor in limiting the scope of claims.[7]

But in other cases, the Federal Circuit has held that statements regarding the 'invention' did not limit the scope of the claims. For example, in *Bio Technology General Corp. v. Duramed Pharmaceuticals, Inc.*, 325 F.3d 1356 (Fed. Cir. 2003), the Federal Circuit refused to read into a claim directed to a "drug delivery system constituted by at least 24 separate daily dosage units" a requirement that all the dosage units be contained in a single package despite the patent's written description that a:

> drug delivery system embodying the present invention contains a pharmaceutical package having at least 24 active dosage units arranged sequentially therein.

Id. at 1362 (emphasis added). In refusing to limit the claims to this description, the Federal Circuit explained that "characterizing a particular drug delivery system as 'embodying' the

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[7] For example, the Federal Circuit recognized in *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 907 (Fed. Cir. 2004), that "in *Watts*, the court held that the applicants specifically 'limit[ed] the invention' to particular structures by specifying that the invention uses those structures, and further limited the scope of the invention by distinguishing close prior art in the prosecution history." In *Alloc*, the Federal Circuit limited the claimed methods of laying and joining interlocking floor panels to those that included "play" because the character of the invention required "play" and because the patentee "expressly disavowed systems without play during prosecution" to distinguish prior art. 342 F.3d at 1369-72. And in *Microsoft*, the Court found that the specification and prosecution history required the claim terms to be limited to communications directly over a telephone line. 357 F.3d at 1347-51. Those facts simply have no application here.

invention is not the same as stating that the term 'drug delivery system' is limited to that embodiment." *Id.* The Court then also found no evidence in the rest of the intrinsic record that the patentee intended to limit the drug delivery system claims to a single package. *Id.*

So too here, the Court should look to the entire intrinsic record to determine if Wyeth intended to limit its method claims to specific formulations or specific ingredients. Wyeth submits that there is no such evidence. In fact, the intrinsic record evidences just the opposite: (1) in the claims (where the independent method claims omit specific ingredients present in the independent formulation claims, and where dependent method claims recite ingredients that Impax seeks to read into the independent method claims), (2) in the specification (where the "use aspect of the invention" is not limited to specific formulations or specific ingredients), and (3) in the prosecution history (where the evidence shows the patent examiners interpreted the method claims as not being limited to specific formulations or specific ingredients).

Finally, Impax cites two cases to support its argument that the claims should be narrowly construed because the preferred formulations disclosed in the specification include venlafaxine hydrochloride, MCC and, optionally, HPMC. *See Wang Labs, Inc. v. Am. Online Inc.*, 197 F.3d 1377 (Fed. Cir. 1999); *Networld, LLC v. Centraal Corp.*, 242 F.3d 1347 (Fed. Cir. 2001). [Impax Br., D.I. 162, at 13]. This argument is based on an incorrect premise because it focuses on preferred embodiments and ignores the specification as a whole and the remaining intrinsic record. As explained in *Wang*, "[w]hether an invention is fairly claimed more broadly than the 'preferred embodiment' in the specification is a question specific to the content of the specification, the context in which the embodiment is described, the prosecution history, and if appropriate the prior art." 197 F.3d 1383.[8] And here, the specification expressly indicates that the examples are only intended to "illustrate" the "preparation of the extended release . . . formulations of this invention." [Ex. 1, col. 5, ll. 29-32]. Further, the remainder of the

[8] And in both *Wang*, 197 F.3d at 1381-82, and *Netword*, 242 F.3d at 1352-53, the courts found narrowing definitions in the specification.

specification (specifically Table 1), the context (in which a broader "use invention" is disclosed and Table 1 can be used to screen for additional formulations), the prosecution history (which demonstrates that the patent examiners interpreted the method claims as not being limited to a specific formulation), and the prior art (which did not disclose the "use invention" regardless of formulation) compels a conclusion that the claims are not limited to only those therapeutic methods that use the exemplary formulations.

2. Wyeth's Claim Construction Position Has Been Consistent

Although Impax admits that Wyeth's proposed definition in the Teva case "was consistent with the ordinary meaning of 'extended release formulation'," Impax contends that Wyeth has changed its claim construction position since the Teva case. [Impax Br., D.I. 162, at 14-15]. That argument is incorrect.

Although Wyeth did not seek a claim construction in the Teva case that expressly excluded conventional hydrogel tablets, even without that express exclusion the claim construction Wyeth had proposed would not have covered conventional hydrogel tablets. As the patent specification explains, it was impossible to achieve the desired dissolution rates with such tablets. Wyeth's present claim construction simply makes this explicit. In all other respects, as in the Teva case, Wyeth's construction is consistent with what even Impax concedes is the ordinary and customary meaning of "extended release formulation." In any event, none of this supports Impax's proposed claim construction.

3. The Prosecution History Supports, Rather Than Bars, Giving The Term "Extended Release Formulation" Its Ordinary And Customary Meaning

As discussed in Wyeth's Opening Brief at 24-27, D.I. 166, the prosecution history of Wyeth's patents makes clear that the term "extended release formulation" is not limited to or defined by ingredients. Impax does not dispute that in the first non-provisional application in the chain that led to the issuance of the patents-in-suit, Wyeth initially proposed product claims that specified the ingredients in the extended release formulation as well as method claims that recited the term "extended release formulation" without specifying any inactive ingredients.

[Impax Br., D.I. 162, at 5; Ex. 11 at WYETH 002-000804-805]. Although the examiner was prepared to allow the product claims, he suggested that the method claims would be patentable if they were amended so as to depend from the product claims. [Ex. 11 at WYETH 002-000850]. By so doing, the examiner fully recognized that the term "extended release formulation" in the method claims did not require any specific set of ingredients. Stated somewhat differently, the examiner interpreted "extended release formulation" according to its ordinary and customary meaning.[9]

Impax is correct that Wyeth initially agreed to amend the method claims to depend from the narrower formulation claims, that the examiner issued a Notice of Allowance, and that rather than allowing the narrow method claims to issue, Wyeth abandoned the application and refiled a new continuation-in-part application with method claims that were virtually identical to the original unamended claims from the earlier application. [Impax Br., D.I. 162, at 5-6].

Impax ignores, however, that along with the Notice of Allowance, the examiner had made the amendment that made the method claims dependent upon the product claims, and the examiner indicated that if the applicant found the amendment to be unacceptable, the applicant should file an amendment. [Ex. 11 at WYETH 002-000854]. After deciding that the amendment was unacceptable, Wyeth abandoned the application and refiled the continuation-in-part application with the original method claims. [Ex. 11 at WYETH 002-000911; Ex. 12 at WYETH 002-000564-583]. By so doing, the public and the Patent Office were fully informed that the "extended release formulation" of the method invention is not limited to a specific extended release formulation having a defined set of inactive ingredients.

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[9] Although the examiner cited to U.S. Patent No. 5,506,270 to Upton et al. in his Interview Summary, that patent merely provides a litany of various types of dosage forms, such as a bolus form, intermittent-release form, sustained oral administration form, or time-release form, but provides no other formulation details, much less what any pharmacokinetic profile would look like when administered to a human. [Impax Ex. I, col. 5, ll. 13-27]. The Upton patent is one of the references listed on the face of the patents-in-suit [Ex. 1 at page 1, "References Cited"], and Impax is not asserting in this litigation that the Upton patent anticipates any of the claims of the patents-in-suit.

Impax argues that Wyeth did not tell the examiner that was assigned to the refiled continuation-in-part application that a different examiner had rejected virtually identical method claims in the prior parent application, and that Wyeth had agreed to amend the original method claims. [Impax Br., D.I. 162, at 6]. But in the very first paragraph of the refiled continuation-in-part application, Wyeth expressly identified to the Patent Office the serial number (08/821,137) of the earlier filed parent application [Ex. 12 at WYETH 002-000569], and the examiner had those files available to him. Indeed, in the context of examining continuing applications under 37 C.F.R. 1.53(b), like the refiled continuation-in-part application here [Ex. 12 at WYETH 002-000565], the Manual of Patent Examining Procedure ("MPEP") expressly instructs patent examiners to "consider information which has been considered by the Office in a parent application when examining: . . . (C) a continuation-in-part application filed under 37 CFR 1.53(b)." [Ex. 25, MPEP § 609.02(A)(2) at 600-148 (Rev. 5, Aug. 2006)]. It also instructs examiners that "[i]n all continuation and continuation-in-part applications, the parent applications should be reviewed for pertinent prior art." [Ex. 26, MPEP § 707.05 at 700-116 (Rev. 5, Aug. 2006)].[10] Moreover, the second examiner was fully aware of the publication that the previous examiner had asserted against the method claims (Upton), and nonetheless allowed the refiled method claims to issue without any rejection or amendment.[11] Most importantly, the

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[10] The MPEP provisions in effect in 1996, when the first Wyeth application was filed, and in October 1998, when the second examiner decided to allow the unamended method claims [Ex. 12 at WYETH 002-000715-721], do not substantially differ from the August 2006 versions of MPEP §§ 609.02(A)(2) and 707.05. [Ex. 28 at 600-103 and 700-56; Ex. 27 at 600-91 and 700-52].

[11] Impax asserts that the second examiner did not allow the unamended method claims until "[a]fter another abandonment and re-filing." [Impax Br., D.I. 162, at 6]. That is not correct. The unamended method claims were allowed in the first refiled continuation-in-part application (Serial No. 08/964,328). [Ex. 12 at WYETH 002-000715-721 at WYETH 002-000716 (allowing claims 13 and 14)]. Impax's assertion that Wyeth was shopping for examiners is belied by the fact that even though the method claims had been allowed, Wyeth abandoned the application and refiled another continuation-in-part application [Ex. 12 at WYETH 002-00764; Ex. 13 at WYETH 002-000012], which later issued as the '171 patent.

refiled method claims that were allowed, which correspond to the method claims at issue here, contain no inactive ingredient limitations.

The prosecution history outlined above leaves no doubt what the claims themselves make clear, namely, that Wyeth's method claims are not restricted to any specific set of inactive ingredients. Unable to challenge this conclusion, Impax argues that Wyeth should be barred from enforcing the full scope of the refiled claims that issued as Wyeth's method claims. In essence, Impax wants the Court to replace the actual method claims in Wyeth's patents with the amended method claims that Wyeth refused to accept. The only case Impax cites for this unprecedented proposition is *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313 (Fed. Cir. 2007). But *Hakim* does not support Impax's radical assertion.

In *Hakim*, the parent application had claims directed to a drinking cup with a flexible valve material having a slit. During prosecution of that application, the applicant argued a restrictive claim construction to distinguish prior art references. Specifically, the applicant argued:

> None of the references cited in the Office Action . . . teach or suggest such a no-spill mechanism having a slit sitting against a blocking element such as is recited in all of the pending claims.

Hakim, 479 F.3d at 1316 (emphasis in original). Thus, as the Federal Circuit recognized, the presence of the slit in the flexible valve material "was emphasized as distinguishing all of the claims from the cited references." *Id.*

After a Notice of Allowance issued, the applicant refiled the application replacing the word "slit" in the claims with "opening." Although the applicant included a letter with the continuing application indicating that the claims were broadened by changing "slit" to "opening", he did not withdraw the previous arguments he made in distinguishing the invention over the prior art. In construing the claims in the patent, the district court interpreted "opening" to mean slit. According to the Federal Circuit:

> [T]he district court held Hakim to his arguments in the parent application that the invention includes the presence of a slit in the flexible material. The court stated: "Because Hakim did not retract any of his arguments

> distinguishing the prior art, he is held to the restrictive claim construction he argued during prosecution of the patent."

Id. (quoting from the District Court opinion). In affirming the lower court, the Federal Circuit stated:

> [A]n applicant cannot recapture claim scope that was surrendered or disclaimed. **The district court did not err in holding that the examiner's action in allowing the continuation claims without further prosecution was based on the prosecution argument in the parent**. . . . Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited . . . .

Id. at 1317-18 (emphasis added) (citations omitted).

Thus, the *Hakim* court interpreted the term "opening" in the refiled claims to mean "slit," as used in the original claims, because: (1) the patent applicant had argued in the original application that his invention required a slit to distinguish over prior art that did not have a slit, and (2) the examiner allowed the refiled claims based on the prosecution argument in the parent application. By contrast here, Wyeth made no claim construction argument (or any other argument) to the first examiner to distinguish the claims over the prior art, and consequently there were no arguments to rescind. And most importantly, the prosecution history makes clear that the second examiner did not rely upon a narrow claim construction in deciding to allow the method claims.

Specifically, during the parent application, the first examiner indicated that the method claims would be allowed if they were amended to depend from the product claims. The examiner made that amendment, but expressly indicated:

> Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

[Ex. 11 at Wyeth 002-000850-855 at 854]. As the first examiner recognized, Wyeth was not bound by the amendment, and in fact decided not to accept the amendment. Instead, Wyeth refiled the application with the original unamended method claims. Unlike in *Hakim*, Wyeth

made no prior statements interpreting Wyeth's method claims, or distinguishing Wyeth's method claims over the prior art.

Moreover, while the examiner in the refiled application in *Hakim* relied upon the narrowing arguments the applicant had made in the parent in allowing the refiled claims, here there is no question that the second examiner interpreted "extended release formulation" in accordance with its ordinary meaning. Specifically, in the refiled continuation-in-part application, Wyeth added product claims (claims 17 and 18) that depended from independent method claim 14 and that recited specific ingredients of the extended release formulation. [Ex. 12 at WYETH 002-000583]. The examiner objected to claims 17 and 18, stating:

> Claims 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The formulation of claims 17 and 18 improperly depends on claim 14 a method since claim 14 does not recite any limitations describing the formulation.

[Ex. 12 at WYETH 002-000718 (emphasis added)]. Thus, the examiner understood that the term "extended release formulation" in the method claims as "not recit[ing] any limitations describing the formulation." Consequently, unlike in *Hakim*, the second examiner did not rely on any statements or actions by Wyeth in the parent application in construing the refiled method claims or in deciding to allow those claims.

In essence, the *Hakim* case, and the cases cited in *Hakim*, simply focus on the public notice function of a patent and its prosecution history. Here, the public was notified that Wyeth did not accept the examiner's amendment to the method claims that would have restricted those claims to specific ingredients. Consistent with the examiner's suggestion, Wyeth abandoned the application with the amended method claims, and refiled the application with no amendment to the method claims. Those unamended method claims contain no recitation of specific inactive ingredients for the extended release formulation. The examiner allowed those claims as refiled, with no amendment, and recognized that the method claims recite no limitations on the formulation. The public notice provided by this prosecution history rings loud and clear: the

method claims are not restricted to any specific set of inactive ingredients. Impax now wants to ignore that public notice and simply rewrite the prosecution history to avoid literal infringement. *Hakim* provides no support for this unprecedented proposal.

B. Diminished Incidences Of Nausea And Emesis

With respect to "diminished incidences of nausea and emesis," Impax fails to focus on the actual claim language. When Impax turns to the specification, it downplays the discussion of an important benefit of Wyeth's patents, and proposes a claim construction that illogically excludes that benefit.

1. Impax's Proposed Construction Ignores The Word "Diminished" And Ignores Its Own Definition Of "Incidence"

Impax's proposed construction of "diminished incidences of nausea and emesis" again ignores the claims themselves. In particular, Impax ignores the word "diminished," which does not appear in the specification and which means "to reduce in size, number, or degree." [Wyeth Br., D.I. 166, at 31].

Moreover, Impax's proposed construction ignores its own definition of "incidences." Impax argues that "the incidence of nausea and emesis refers to the frequency of nausea and emesis within the patient population." [Impax Br., D.I. 162, at 17]. If that definition is applied to two patients, one who was administered Effexor and experienced nausea and emesis every day over a one month period and a second who was administered Effexor XR and experienced nausea and emesis on only the first two days of the same period, plainly the second patient experienced less frequent nausea and emesis (i.e., a reduced incidence of nausea and emesis). But under Impax's construction ("a decrease in the number of patients suffering from nausea and emesis"), both patients would be categorized as "patients suffering from nausea and emesis," with no difference between the patients. [Ex. 29 at 5-6]. Thus, Impax's proposed construction does not comport with its own definitions. Moreover, Impax's proposed construction is artificial and illogical because clearly the second patient suffered fewer side effects.

2. Impax's Proposed Claim Construction Is Premised On Extrinsic Evidence Which Is At Odds With The Intrinsic Record

Impax's entire claim construction argument is premised on extrinsic evidence—an expert declaration purporting to describe how one skilled in the art understands the words "incidence" and "level." [Impax Br., D.I. 162, at 17]. Elsewhere, however, Impax argues that extrinsic evidence is "less significant" and "less reliable" than intrinsic evidence. [Impax Br., D.I. 162, at 8].

Impax's expert declares that "[i]ncidence refers to the number of patients who experience an event" and "[l]evel refers to the severity or intensity of an event." [Impax Br., D.I. 162, at 17-18]. He is silent, however, as to whether "incidence" encompasses "the frequency of an event." Moreover, he offers no explanation for why the claims should be construed to exclude improvements in adaptation to a drug (fewer and less severe side effects over time), particularly where the specification discusses that improvement. Indeed, Impax's expert completely ignores the discussion of adaptation in the specification. As cautioned in *Phillips*, "a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc).

Wyeth's expert, on the other hand, has interpreted the claim language in the context of the specification and the inventions disclosed therein. He concludes that the phrase "diminished incidences of nausea and emesis" encompasses not only less frequent nausea and emesis but also reductions in the degree (severity, duration, intensity, etc.) of those side effects. [Wyeth Br., D.I. 166, at 34; *see also* Ex. 29 at 4-7].

3. Impax Cites Selectively From The Specification And Misstates What It Does Cite

Impax argues that "incidence" must mean something different from "level" because the specification refers to reducing the "level of nausea" and "incidence of emesis." [Impax Br., D.I. 162, at 18]. This argument begs the question as to what is meant by the word "incidence." Moreover, the claim language "diminished incidences of nausea and emesis" suggests that the

measure of improvement (fewer patients who suffer these side effects, less frequent side effects, or less severe side effects) is the same for measuring both nausea and emesis. Thus, the specification's reference to reducing the "level of nausea" and "incidence of emesis" suggests that the phrase "diminished incidences of nausea and emesis" must encompass reductions in the level of nausea and incidence of emesis. In other words, "diminished incidences of nausea and emesis" includes reducing "the degree and/or frequency" of nausea and emesis.

Impax also relies on the Abstract, which states that the invention "provides a lower incidence of nausea and vomiting than conventional tablets." Impax then embraces Judge Martini's conclusion that "[b]ecause the only discussion of the conventional tablets in the specification that is relevant to the term incidence concerns the percent of patients that experienced side effects, the abstract supports a narrow construction." [Impax Br., D.I. 162, at 18]. That conclusion, however, is simply incorrect. The specification includes a discussion devoted to improvements in "adaptation" to extended release venlafaxine formulations as compared to immediate release formulations. [Ex. 1, col. 2, ll. 46-62]. As the specification explains:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing.

[Ex. 1, col. 2, ll. 46-49].

This passage plainly does not support Impax's claim construction because patients who quickly adapt to extended release formulations would fall outside the scope of Impax's construction because they still suffered some degree of nausea and vomiting earlier. [Ex. 29 at 4-6]. Impax cites the Teva Markman ruling and *Liebel-Flarsheim Co. v. Medrad, Inc*, 358 F.3d 898 (Fed. Cir. 2004), for the proposition that claims need not be construed as limited to structures that are capable of achieving all the invention's objectives. [Impax Br. at 19]. But *Liebel-Flarsheim* is a case where the court refused to limit the claims to only structures that performed every objective described in the specification, not a case where the court's claim construction excluded structures that met the objectives of the invention, as Impax implies. *See*

Liebel-Flarsheim, 358 F.3d at 907-909. Moreover, claims should be construed consistent with the "fundamental purpose and significance of the invention," as reflected in the specification. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1364 (Fed. Cir. 2001) (quoting the District Court). And here the specification establishes that reducing the degree and/or frequency of nausea and emesis is consistent with the purpose and significance of the patented inventions.

Lastly, it is ironic that Impax argues that "[i]t is not this Court's task to rewrite the claims, but merely to determine what the claims as written mean." [Impax Br., D.I. 162, at 19]. Impax's entire case on "extended release formulation" is contingent on a massive redrafting of Wyeth's patent claims. In any event, Wyeth agrees that the Court should not rewrite the claims. Adding a litany of ingredients to Wyeth's method claims, under the guise of interpreting a term that has a well-established ordinary meaning ("extended release formulation"), is a poster child for rewriting claims. By contrast, interpreting "incidence" so as not to exclude a clearly defined benefit discussed in Wyeth's specification is not rewriting claims.

C. Eliminating Troughs And Peaks

Impax does not want the Court to construe the phrase "eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" because it wants to argue that the term "therapeutic metabolism" is "indefinite," a defect that would invalidate the claims reciting this limitation. To advance this defense, Impax contends that "therapeutic metabolism" has no ordinary meaning in the art, and then argues that attempting to interpret the term is "futile." [Impax Br., D.I. 162, at 20]. Instead of throwing up its hands in "futility," however, the Federal Circuit instructed today that "[w]ithout a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning." *Honeywell*, slip op. at 9 (Fed. Cir. May 25, 2007) (attached as Ex. A hereto). That is precisely what Wyeth has done in construing this term.

Impax also complains that Wyeth's proposed construction of the entire phrase should be rejected because it is too detailed (i.e., too narrow), an unusual complaint coming from an

accused infringer. Its approach also is inconsistent with its arguments on "extended release formulation," where Impax relies on the narrowest conceivable interpretation. Thus, Impax's alleged inability to interpret the disputed phrase in this instance should be greeted with suspicion.

1. The Term "Therapeutic Metabolism" Can Be Interpreted In The Context Of The Entire Claim Limitation And In Light Of The Specification

The term "therapeutic metabolism" should not be viewed in isolation, but rather viewed in the context of the phrase in which it appears, "eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride." The specification makes clear that the "metabolism" referenced in the claim is the metabolism that occurs following administration of venlafaxine, which causes the blood plasma level of the drug to fall below therapeutic levels:

> In therapeutic dosing with venlafaxine hydrochloride tablets, rapid dissolution results in a rapid increase in blood plasma levels of the active compound shortly after administration followed by a decrease in blood plasma levels over several hours as the active compound is eliminated or metabolized, until subtherapeutic plasma levels are approached after about twelve hours following administration, thus requiring additional dosing with the drug.

[Ex. 1, col. 1, l. 66 - col. 2, l. 7 (emphasis added)]. This is the only express reference to "metabolism" in the specification. The specification goes on to say that the claimed invention eliminates the rapid increase and decrease (sharp peaks and troughs) in blood plasma drug levels associated with administration of multiple daily doses of an immediate release formulation followed by metabolism of the drug:

> In other words, this invention provides a method for eliminating the sharp peaks and troughs (hills and valleys) in blood plasma drug levels induced by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets.

[Ex. 1, col. 2, ll. 24-28]. Thus, the term "therapeutic metabolism" simply means the metabolism that occurs when therapeutic doses of venlafaxine are administered to a patient. [Ex. 29 at 1-4].

That Impax chooses to provide no construction for "therapeutic metabolism" to foster its indefiniteness defense does not make the term incapable of interpretation. As recognized in

Exxon Research & Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (citations omitted), cited by Impax [Impax Br., D.I. 162, at 20]:

> If the meaning of the claim is discernable, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.

And as recognized in *Metabolite Laboratories., Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004), only when a claim remains "insolubly ambiguous" without a discernable meaning after all reasonable attempts at construction can a Court declare it indefinite. For the reasons discussed above, "therapeutic metabolism" is readily amenable to construction. It is not a term that, even after the application of "formidable" efforts, remains "insolubly ambiguous."

2. The Specification Supports Wyeth's Proposed Claim Construction Of "Eliminating The Troughs And Peaks"

Impax complains that Wyeth's proposed construction "adds no fewer then [sic] 9 limitations to the claim" and takes a "relatively simple concept of once-a-day dosing and converts it into a complicated graph." [Impax Br., D.I. 162, at 21]. Wyeth has done nothing more than interpret the words in dispute, such as "eliminating the troughs and peaks of drug concentration in a patients blood plasma. . . ." Wyeth has simply asked the Court to look to the words of the claim and the specification to construe this phrase.

Impax resists construing this phrase with precision, characterizing its construction as "simple" and complaining that Wyeth's construction is "complicated." Although Impax criticizes Wyeth's construction because it "seems literally to require a graph. . ." [Impax Br. at 21], "troughs and peaks in a patients blood plasma" are not seen through a microscope, but rather are visualized with a graph of drug concentration versus time.

Impax further argues that "the preamble does not provide any insight as to the specific shape of a graph of the drug concentration in a patient's blood plasma." [Impax Br., D.I. 162, at 22]. But here too, the specification fully supports Wyeth's proposed interpretation. For example, after explaining that the invention "eliminat[es] the sharp peaks and troughs" in blood

plasma drug levels associated with "multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets" [Ex. 1, col. 2, ll. 24-28], the specification elaborates in the next sentence as follows:

> In essence, the plasma levels of venlafaxine [] hydrochloride rise, after administration of the extended release formulations of this invention, for between about five to about eight hours (optimally about six hours) and then begin to fall through a protracted, substantially linear decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four [hour] period.

[Ex. 1, col. 2, ll. 28-36]. Wyeth's proposed claim interpretation simply reflects this paragraph in its proposed construction of "eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride."

V. CONCLUSION

For the reasons discussed above and in Wyeth's Opening Markman Brief, Wyeth respectfully requests that the Court adopt Wyeth's construction of the three disputed claim terms:

> "**extended release formulation**": a formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation;
>
> "**diminished incidences of nausea and emesis**": the degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day; and
>
> "**a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride**": a method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release

formulation as reflected in a graph of venlafaxine blood plasma concentration versus time.

Respectfully submitted,

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden (#2881)

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Chase Manhattan Centre, 18th Floor
1201 North Market Street
Wilmington, DE 19801
(302) 658-9200
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Barbara R. Rudolph
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

May 25, 2007

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on June 4, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filings(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on June 4, 2007, upon the following in the manner indicated:

BY HAND AND E-MAIL

Mary B. Matterer
Morris, James, Hitchens & Williams
500 Delaware Avenue
Suite 1500
Wilmington, DE 19899

BY E-MAIL AND BY FEDERAL EXPRESS

M. Patricia Thayer
John M. Benassi
Jessica R. Wolf
Heller Ehrman LLP
4350 La Jolla Village Drive
San Diego, CA 92102

Joseph C. Gratz
Keker & Van Nest LLP
710 Sansome Street
San Francisco, CA 94111

/s/ Karen Jacobs Louden
klouden@mnat.com

EXHIBIT A

United States Court of Appeals for the Federal Circuit

05-1112, -1151, -1152

HONEYWELL INTERNATIONAL INC. and
HONEYWELL INTELLECTUAL PROPERTIES INC.,

Plaintiffs-Appellants,

v.

UNIVERSAL AVIONICS SYSTEMS CORP.,

Defendant-Cross Appellant,

and

SANDEL AVIONICS INC.,

Defendant-Cross Appellant.

Steven D. McCormick, Kirkland & Ellis, LLP, of Chicago, Illinois, argued for plaintiffs-appellants. With him on the brief was Christopher Landau, of Washington, DC. Of counsel on the brief was Sarah Sklover, Mayer Brown Rowe & Maw LLP, of New York, New York. Of counsel was John C. O'Quinn.

Scott J. Bornstein, Greenberg Traurig, LLP, of New York, New York, argued for defendant-cross appellant Universal Avionics Systems Corp. With him on the brief was William G.Todd.

Howard G. Pollack, Fish & Richardson P.C., of Redwood City, California, argued for defendant-cross appellant Sandel Avionics, Inc. With him on the brief were Frank E. Scherkenbach, of Boston, Massachusetts, Michael R. Headley, of Redwood, California, and John A. Dragseth, of Minneapolis, Minnesota.

Appealed from: United States District Court for the District of Delaware

Magistrate Judge Mary Patricia Thynge

United States Court of Appeals for the Federal Circuit

05-1112, -1151, -1152

HONEYWELL INTERNATIONAL INC. and
HONEYWELL INTELLECTUAL PROPERTIES INC.,

Plaintiffs-Appellants,

v.

UNIVERSAL AVIONICS SYSTEMS CORP.,

Defendant-Cross Appellant,

and

SANDEL AVIONICS INC.,

Defendant-Cross Appellant.

DECIDED: May 25, 2007

Before RADER, GAJARSA, and DYK, Circuit Judges.

RADER, Circuit Judge.

In a series of decisions on summary judgment, the United States District Court for the District of Delaware invalidated certain claims and found no infringement of patents owned by Honeywell International Inc. and Honeywell Intellectual Properties Inc. (Honeywell). Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 343 F. Supp. 2d 272 (D. Del. 2004) (Final Decision); Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 264 F. Supp. 2d 135 (D. Del. 2003) (Claim Construction Decision); Honeywell Int'l, Inc., v. Universal Avionics Sys. Corp., 288 F. Supp. 2d 638 (D. Del. 2003)

(Invalidity Decision); Honeywell Int'l, Inc., v. Universal Avionics Sys. Corp., 289 F. Supp. 2d 493 (D. Del. 2003) (Non-infringement Decision). Honeywell contests issues of claim construction, infringement, and subject matter jurisdiction on a few claims withdrawn from the litigation. Universal Avionics Systems Corp. (Universal) and Sandel Avionics Inc. (Sandel) cross-appeal the district court's final decision that other remaining claims were not barred by public uses or premature sales activity. Final Decision, 343 F. Supp. 2d at 309. In addition, Sandel appeals the district court's determination that Honeywell did not commit inequitable conduct. Id. at 313. Universal further appeals the district court's denial of its commercial counterclaims. Final Decision, 343 F. Supp. 2d at 319. Finding errors, this court vacates the claim construction of a few terms and remands for a new infringement determination. This court affirms the district court's retention of jurisdiction over the withdrawn claims and the district court's decision that § 102(b) does not erect a bar.

I

This patent infringement case involves aviation electronics, specifically terrain warning systems. "Terrain warning systems" warn pilots to prevent them from flying into a mountain or hillside. This type of accident is called a "controlled flight into terrain" (CFIT).

Air travel has benefited from terrain warning technology for approximately thirty years. The prior art technology, known as "ground proximity warning systems" or (GPWS), sharply reduced CFIT accidents beginning in the 1970s and 80s. This GPWS technology, however, featured a number of limitations. GPWS technology used radio waves to measure the distance of the aircraft above the ground. Using the downward

looking information from the radio altimeter, GPWS technology tried to predict the threat of CFIT posed by terrain near the aircraft. This system worked well for gradual changes in terrain. The GPWS system, however, provided no reliable warnings in abruptly changing terrain. In sum, the prior art did not provide information regarding the terrain ahead of the aircraft.

Honeywell began research in the 1980s aimed at developing a "look ahead" terrain warning system. Without forward-looking radar or forward-looking sensors aboard civilian aircraft, Honeywell's research focused on a "virtual" look ahead system. This virtual system would not physically detect the terrain ahead of the aircraft but instead would compare the aircraft's position with an on-board digitized map of the earth's terrain and man-made obstacles. In 1995, Honeywell received patent protection for its virtual look ahead system, including the five patents-in-suit: U.S. Patent Nos. 5,839,080 (the '080 patent), 6,092,009 (the '009 patent), 6,122,570 (the '570 patent), 6,138,060 (the '060 patent), and 6,219,592 (the '592 patent). These patents fall into two main categories: the "look ahead patents" ('080, '570, and '592) and the "display patents" ('060 and '009).

The patented technology works as a system of algorithms that define a volume of space referred to as an alert envelope. The alert envelope is defined by: (1) the aircraft's flight path, (2) the look ahead distance, and (3) the terrain boundary floor. This alert envelope takes into account the position and speed of the aircraft as well as the flight path. The system then searches the database of digitized maps and warns about any terrain or obstacles within the alert envelope. The system refers to alert distance in front of the aircraft as the "look ahead distance." The distance that the system looks

below the aircraft depends on a safe terrain clearance value, referred to as a "terrain floor boundary." This boundary varies as a function of the aircraft's distance from a reference point, such as an airport or runway. The look ahead patents disclose the inputs into the system, the definition of alert inputs, and the output alerts. The display patents disclose and claim various methods for providing representations of the terrain surrounding the aircraft, including the display of the contours of threatening terrain.

Honeywell contacted the FAA in early 1995 seeking certification for its "look ahead" terrain warning system. Honeywell called its system an "Enhanced Grand Proximity Warning System" or "EGPWS." In 1996, stemming from the CFIT accident that claimed the life of Commerce Secretary Ron Brown, the United States Congress pressured the FAA to issue regulations raising the requirements for CFIT prevention technology. The FAA now requires that all commercial aircraft of a certain size include a look ahead warning system.

Following the release of FAA's system requirements, Universal and Sandel began to develop competing terrain warning systems. Universal introduced its certified system, which it called TAWS, in 2000. Sandel announced its system, which it called the ST3400 TAWS/RMI in 2000. Both the Universal and Sandel systems are virtual look ahead systems. Sandel asserts, however, that its device lacks at least five limitations in the asserted patent claims. Similarly, Universal argues that the asserted claims as construed by the trial court do not cover its system.

Honeywell brought suit against Universal and Sandel in the District of Delaware in 2002.[1] The district court construed the claims in a Memorandum Opinion dated May 30, 2003. Claim Construction Decision, 264 F. Supp. 2d at 135. On October 16, 2003, the district court granted defendants' motions for summary judgment of invalidity of certain claims that had been withdrawn from the litigation. Invalidity Decision, 288 F. Supp. 2d at 638. The district court granted defendants' summary judgment motions of non-infringement on October 28 and 29, 2003. Non-infringement Decision, 289 F. Supp. 2d at 493. The district court denied all of defendants' remaining counterclaims of invalidity during a seven-day bench trial which began on November 2, 2003. Final Decision, 343 F. Supp. 2d at 272.

II

Honeywell appeals the district court's construction of five claim terms. This court reviews claim construction without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998). Claim one of the '080 patent contains four of those five contested claim terms, including the claim terms "signals representative of," "look ahead distance," "alert envelope," and "terrain floor boundary." These terms mean the same thing in each patent. Claim 1 of the '080 patent recites:

> An apparatus for alerting a pilot of an aircraft of proximity to terrain, the apparatus comprising:
>
> an input for receiving signals representative of a position of the aircraft, a flight path angle of the aircraft and a speed of the aircraft and coupled to a data base of stored terrain information;

[1] The case was originally assigned to the Honorable Roderick McKelvie, but after he announced his departure from the bench the parties agreed to have the case tried by Magistrate Judge Mary Patricia Thynge.

an output;

a signal processing device, coupled to said input, and coupled to said output, for:

(a) defining a look ahead distance as a function of the speed of the aircraft;

(b) defining a first alert envelope, indicative of a first severity of terrain threat,

wherein boundaries of said first alert envelope are determined as a first function of the flight path angle, said look ahead distance, and a terrain floor boundary;

(b) [sic] defining a second alert envelope, indicative of a second severity of terrain threat, wherein boundaries of said second alert envelope are determined as a second function of the flight path angle, said look ahead distance and said terrain floor boundary; and

(d) outputting an alert signal when a subset of the stored terrain information is located within the boundaries of at least one of the said first and said second alert envelopes.

(emphases added).

The one remaining contested claim term —highest h_{max} and lowest h_{min}— appears only in the '009 patent, one of the display patents. Independent claim 1 of the '009 patent recites:

An aircraft terrain information system for providing a visual display to the pilot of the contours of the terrain proximate to the aircraft, the warning system comprising:

position means for receiving signals representative of the position of the aircraft terrain data means for storing terrain data representative of terrain elevations;

a cockpit display; and

contour means, responsive to said position means and said terrain data means, for displaying on said cockpit display a display of the contours of at least a portion of the terrain proximate to the aircraft wherein said

> contour display includes the highest h_{max} and lowest h_{min} terrain levels of said portion of the terrain.

(emphasis added).

Only two of the five contested terms contributed to the summary judgment of non-infringement. Universal advises this court to construe only the terms "look ahead distance" and "terrain floor boundary" because those terms controlled the district court's infringement determination. Without citing any authority, Universal argues that this court may not have jurisdiction to consider the construction of the remaining claim terms. However, the district court discerned factual issues in dispute regarding infringement of those remaining terms. Thus, this court proceeds to evaluate all five contested terms.

A. "Look ahead distance"

Claim 1 of the '080 patent requires a signaling device for "defining a look ahead distance as a function of the speed of the aircraft." The district court construed the term "look ahead distance" to mean "a distance along the ground track of the aircraft that marks the outer limit of each alert envelope that is a function of aircraft speed and time to complete an evasive maneuver." Claim Construction Decision, 264 F. Supp. 2d at 146.

Honeywell argues that the correct construction of this term would define the distance the system looks ahead of the aircraft as a function of speed of the aircraft, according to the language of the claim. While the specification describes in detail the manner in which Honeywell calculates the time component of the look ahead distance in its preferred embodiment, the claim itself includes no limitation regarding the time

component, asserts Honeywell. Thus, Honeywell argues the district court improperly read a limitation into the claim from a preferred embodiment.

The district court correctly construed "look ahead distance." "Look ahead distance" is not a term of art. As the record shows, time is inherent in the calculation of "look ahead distance." Usage within the patent makes clear that the purpose of the "look ahead distance" limitation is to allow time to make an evasive maneuver. The specification states that "look ahead distance" is a function of airplane speed and "look ahead time." '080 patent col.9 ll.14-15. "Look ahead time" is thus the time necessary to make an evasive maneuver. In the preferred embodiment, the patent describes "look ahead distance" as the sum of time for "a single turning radium," time for "terrain clearance at the top of the turn," and "a predetermined reaction" time. '080 patent col.9 ll.16-19; see also '080 patent FIGURE 5. Given the clear purpose of the "look ahead distance" limitation, this court concludes that the district court correctly construed it to mean "[a] distance along the ground track of the aircraft that marks the outer limit of each alert envelope and that is a function of aircraft speed and time to complete an evasive maneuver."

However, even under the district court's claim construction, this court finds that the grant of summary judgment was improper. The record shows a genuine issue of material fact because there is evidence that the allegedly infringing devices were also set to provide a warning that allows time to conduct an evasive maneuver. As the district court noted, Sandel's system provides a "caution" alert at 60 seconds, which is called the "time to impact scheme," and a "warning" alert at 30 seconds. Expert testimony noted that Sandel's system provided "the pilot time to decide what is the best

course of action under the unique circumstances presented." Universal's system also uses a fixed "time to impact," which is set to a default of 30 and 60 seconds. Documents that were part of the summary judgment record specifically suggest that the "look ahead" feature allowed "time for the pilot to make the necessary maneuvers or data corrections for terrain avoidance." Accordingly, this court remands on the question of whether the allegedly infringing devices infringe under the district court's construction of "look ahead distance."

B. "Terrain Floor Boundary"

Claim 1 of the '080 patent further requires alert envelopes which are calculated in part by a measurement of the "terrain floor boundary." The district court construed the term to mean "a boundary that extends downwardly below the aircraft which is proportional to the distance to the closest runway." Claim Construction Decision, 264 F. Supp. 2d at 150 (emphases added). Honeywell finds no limitation in the claim tying this term to a proportional distance to the closest runway. Again, Honeywell argues that the district court incorrectly read a limitation from the specification into the claim.

As the district court correctly noted, the term "terrain floor boundary" had no ordinary meaning to a skilled artisan at the time of filing of the patent application. Id. at 151 ("Further, there is no evidence to indicate that 'terrain floor boundary' was a term having ordinary meaning known to one skilled in the art at the time of the filing of the patent application."). Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning. Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir. 2004). Here, the specification states: "The terrain floor boundary is the basis for the terrain threat

boundaries and is similar to the terrain floor developed for the GPWS." '080 patent col.10 ll.38-40. The patent then explains: "The terrain floor relates to a distance ΔH below the aircraft and is proportional to the distance to the closest runway to prevent nuisance warnings when the aircraft is taking off and landing . . . ." '080 patent col.10 ll.40-42 (emphasis added). The district court used this general language about the terrain floor as its primary reference for defining "terrain floor boundary." While Honeywell notes that the patent proceeds later to discuss "terrain floor boundary" more specifically as a "function of the distance from the runway," '080 patent col.11 ll.18-19 (emphases added), and again, in the discussion of terrain warning boundaries, the patent defines the ΔH terrain floor as "a function of the distance from a runway," '080 patent col.12 ll.8-10 (emphases added), this function is defined in the specification as distance proportional to the closest runway. As such, this court disagrees with Honeywell that the district court improperly read a limitation from the specification into the claim.

However, this court again finds that while the district court correctly construed the term, its finding of non-infringement by Sandel and Universal was erroneous. The Universal device calculates terrain floor boundary as a function of the destination runway. However, Universal's software requirements state that when the airplane deviates from the flight plan, the software redefines the destination as the airport and runway "with the closest Runway Threshold." Sandel's device calculates the terrain floor boundary—which Sandel calls "clearance buffer"—as a function of the distance to the closest runway and the altitude of the airplane. Sandel's CEO, Gerald Block, testified that Sandel's "clearance buffer" "is based on both the distance of the airplane

from and the altitude of the airplane above the weighted average distance of the nearest runways or airport reference points." Thus this court discerns issues of material fact regarding whether the accused devices infringe the "terrain floor boundary" limitation as construed by the district court.

C. "Signals Representative Of"

Claim 1 of the '080 patent further requires that the apparatus have "an input for receiving signals representative of a position of the aircraft, a flight path angle of the aircraft and the speed of the aircraft coupled to a data base of stored terrain information." (emphasis added). The district court interpreted the phrase "signals representative of" to mean "[t]he signals received by the apparatus are instantaneous values of the recited variables; i.e. they indicate the numerical value of that variable at a given sampling time." Claim Construction Decision, 264 F. Supp. 2d at 145. In explaining this claim construction, the district court stated:

> Honeywell argues that its patent covers any signal relating to the angle, position, and speed of the flight . . . The terrain awareness systems compare flight data with stored terrain information, in order to warn the pilots of danger. If the court construed Honeywell's patent to include any signal representing one of the previously mentioned variable, it would claim both signals which indicate threat, and signals which do not. Since the point of the invention is to warn of dangerous conditions, the patent should be limited to signals which represent threat. Because a pilot cannot read a signal, the signals are transformed into numbers, thus "dangerous signals" are understood in terms of numbers . . . Thus, reading the patents in the broad manner that Honeywell proposes, that is, allowing the patents to apply to the entire spectrum of signals, would defeat the purpose of the patent.

Id. at 145-46.

Honeywell argues on appeal that the district court unduly narrowed the term "signals." Honeywell contends that the term should encompass any electronic, visual,

audible, or other ways to convey such information. Further, Honeywell argues that "signals representative of" are, by definition, such signals that represent or portray. Honeywell argues that nothing in the claims, specification, or prosecution history limits the signals to instantaneous and numerical values.

Universal states that the term "signals representative of" should mean "that the input receives signals from other devices which represent discreet and instantaneous numeric values of recited variables that warn a pilot of dangerous conditions." However, Universal offers no argument to support this interpretation.

Sandel supports the district court's construction as based on the claim language itself; i.e. that the claim requires "signals representative of" position, flight path angle, and speed in calculating distances and creating alert envelopes. According to Sandel, only numerical terms allow the system to function, but Sandel offers no evidence in support of this assertion.

This court has acknowledged: "In some cases, the ordinary meaning of claim language . . . involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. Consistent with that guidance, this court perceives that the signals represent the inputs into the system, namely the position, flight path angle, and speed of the aircraft. The patent does not require numerical or instantaneous signals. In context, one of ordinary skill in this art would consider the district court's construction too narrow.

Apparently the district court unduly narrowed the claim based on its overall perception of the invention. Specifically, the district court assumed that the pilot reads the signals at issue. Claim Construction Decision, 264 F. Supp. 2d at 145-46. To the

contrary, the signals represent the inputs into the system about aircraft position, speed, and flight angle, not a data representation for pilot consumption. The pilot does not read these inputs. Instead the system's software processes these inputs to generate visual and aural warnings. Thus, the trial court erred by stating that the pilot would read these signals.

In sum, one of ordinary skill in this art would not limit this term to numerical or instantaneous values. Rather these signals are inputs into the system which uses its algorithms to process this information into appropriate warnings.

D. "Alert Envelope"

Honeywell appeals the district court's claim construction of the term "alert envelope." Claim 1 of the '080 patent calls for a "first alert envelope" and a "second alert envelope." According to the claim, these indicate a first and second terrain threat. The district court construed "first alert envelope" as a "term of art in avionics and means an at least 2-dimensional region in the vertical plane surrounded by a continuous boundary." Claim Construction Decision, 264 F. Supp. 2d at 148. For the term "second alert envelope," the district court required "two distinct alert zones, the boundaries of which are independently determined by distinct first and second functions of the same variables; specifically flight path angle, look ahead distance, and terrain floor boundary." Id. The district court construed the terms according to its reading of "the language set forth in the claim." Id.

Claim 1 of the '080 patent describes the "first alert envelope" as a determination of the "first function of the flight path angle, said look ahead distance and said terrain floor boundary." Claim 1 of the '080 patent describes the "second alert envelope" as

"indicative of a second severity of terrain threat, wherein boundaries of said second alert envelope are determined as a second function of the flight path angle, said look ahead distance and said terrain floor boundary" and "outputting an alert signal when a subset of the stored terrain information is located within the boundaries of at least one of said first and second alert envelopes."

Once again, the claim itself provides considerable information about its meaning. In part, the district court correctly defined the "alert envelope" as a two dimensional region of space with some detail about the way to determine the boundaries of each envelope. The district court, however, incorrectly added the limitations not found in the specific language of the claim. Specifically, the trial court read in requirements that the alert envelope appear "in the vertical plane" and "surrounded by a continuous boundary." The claim itself explains that "alert envelope" encompasses "an at least two dimensional region whose boundaries are determined as a function of the flight path angle, look ahead distance and terrain floor boundary." In sum, one of skill in this art would agree that the claim defines this term adequately without additional limitations.

E. Highest H_{max} and lowest H_{min}

Finally, Honeywell appeals the district court's claim construction of the requirement of a "highest H_{max} and lowest H_{min}." Claim 1 of the '009 patent requires the terrain display to include "the highest h_{max} and lowest h_{min} terrain levels of said portion of the terrain." The district court construed this phrase to require "that the display show a numeric value for the highest and lowest points." Claim Construction Decision, 264 F. Supp. 2d at 155. The district court stated that "without numeric values, the highest and

lowest points display would be useless to the pilot because he would have no frame of reference of the terrain relative to the aircraft." Id.

Once again, as occurred with the numeric inclusion above, the district court included an unnecessary limitation in the claim. Indeed, dependent claim 21 specifically discloses a display with numeric information. '009 patent col.40 ll.8-10 ("The system of claim 1 wherein said contour means additionally displays on said cockpit display a range value.") As this court has noted, "the claims themselves provide particular meaning to claim terms." Phillips, 415 F.3d at 1314. "Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." Id. (citing Virtonics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed Cir. 1996)). Finally, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 353 F.3d 898, 910 (Fed. Cir. 2004)). Thus, the language of claim 21 is strong evidence against limiting claim 1 to require a numeric display. As such, this court construes the claim phrase "highest h_{max} and lowest h_{min}" to require only an apparatus that shows the highest and lowest points of the terrain within the portion of terrain displayed.

In light of the full context of the claims and intrinsic evidence, this court determines that one of ordinary skill in this art would perceive undue limitations in three of the five contested aspects of the district court's claim construction. On remand, the trial court will have an opportunity to apply this broader claim construction in the context of infringement and validity.

III

The district court precluded Honeywell from relying on the doctrine of equivalents. In fact, the trial court excluded Honeywell's only evidence of equivalents, the deposition testimony of Dr. Hansman. The district court determined that Dr. Hansman's belated testimony on the doctrine of equivalents was defective because it was not contained in his expert report.

The district court set a fixed date for disclosing expert testimony and Honeywell made no mention of the doctrine of equivalents in its expert reports filed on that date. During cross examination for Dr. Hansman's deposition, he did not testify about the doctrine of equivalents other than a statement that he had not formed any opinions on the matter. On the next day, during direct examination by his attorney, however, Dr. Hansman expressed an opinion on equivalents. Dr. Hansman admitted to discussions with his counsel.

On appeal this court must determine whether Honeywell properly supplemented Dr. Hansman's expert report under Fed. Rule of Civ. Proc. 26(e). Evidentiary rulings do not generally raise issues unique to patent law. Therefore, this court applies the law of the appropriate regional circuit to such procedural rulings. Rhodia Chimie v. PPG Indus. Inc., 402 F.3d 1371, 1376-77 (Fed. Cir. 2005) (citing ATD Corp. v. Lydall, Inc., 159 F.3d 534, 548 (Fed. Cir. 1998)). The United States Court of Appeals for the Third Circuit reviews a district court's decision to exclude evidence for abuse of discretion. Rhodia Chimie, 402 F.3d at 1377 (citing Glass v. Philadelphia Elec. Co., 34 F.3d 188, 191 (3rd Cir. 1994)). Even when an exclusion of evidence occasions severe forfeiture for a party, the Third Circuit will not disturb those decisions absent a clear abuse.

Rhodia Chimie noted that the Third Circuit typically considers four factors in evaluating whether the district court properly exercised its discretion:

> (1) the prejudice or surprise in fact of the party against whom the excluded evidence would have been submitted; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of discovery deadline would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the district court's order.

Id. at 1381 (citing In re TMI Litig., 193 F.3d 613, 721 (3d Cir. 1999)). In this case, the district court did not address these factors in its opinion. Rather, the district court simply limited the expert's testimony to information contained in the expert report. The district court cited several cases where courts excluded testimony that fell outside the expert's report.

Honeywell attempts to distinguish these cases as featuring evidence offered on the doorstep of the trial. Thus Honeywell argues, the rule seeks to prevent ambush at trial, which is not the case here. Honeywell argues that Dr. Hansman merely supplemented his testimony in response to evidence from Universal that appeared several days before Dr. Hansman's deposition. However, Dr. Hansman only a day earlier on cross examination expressed no opinion regarding the doctrine of equivalents. With this context, the district court properly perceived the prospect of surprise, or "ambush" with Dr. Hansman's new testimony. After all, he had indicated he had not considered equivalents just a day earlier. Under the circumstances, applying Third Circuit law, this court cannot discern that the district court abused its discretion in excluding Dr. Hansman's deposition testimony.

IV

Honeywell further appeals the district court's October 16, 2003, decision granting defendants' motions for summary judgment of invalidity for claims withdrawn from the litigation. Specifically, Honeywell argues that the district court erred by exercising jurisdiction over defendants' request for declaratory relief on the withdrawn claims of the '009 and '060 patents.

At the district court, Honeywell represented to Universal and Sandel that it would not pursue infringement of these previously asserted claims of the '009 and '060 patents. Based on this representation, Honeywell attempted to withdraw all of the originally asserted display claims, except claims 27-33 of the '009 patent and claims 4-5 of the '060 patent. The district court determined that Honeywell's refusal to withdraw all of the claims in the display patents left the defendants with a reasonable apprehension of suit. As such, the district court maintained jurisditicion over the claims Honeywell sought to withdraw. Ultimately the district court found claims 1-3, 8, 9, 13, 24, 34-36, 41, and 43-45 of the '009 patent and claims 1-3 of the '060 invalid based on anticipation.

The Supreme Court's decision in MedImmune, Inc. v. Genetech Inc., 549 U.S. ____ (2007), recently eliminated this court's "reasonable apprehension of imminent suit" test. Under the new legal regime envisioned by the Supreme Court, this court analyzes whether the district court erred as a matter of law in finding an actual controversy between the parties, as required by the Declaratory Judgment Act, 28 U.S.C. § 2201(a), and Article III of the Constitution.

Of course, infringement of a dependent claim also entails infringement of its associated independent claim. When Honeywell withdrew some independent claims from the litigation, it also chose to maintain causes of action based on certain

dependent claims relating to its display technology. As noted, Honeywell thus left the entire subject matter of the display claims at issue. This case differs from the situation in Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902, 905 (Fed. Cir. 1988), which Honeywell cites for support. In Grain Processing, the patentee agreed not to assert an entire group of process claims that had initially formed a basis for the complaint, leaving at issue only the four asserted product claims. Id. at 904. Honeywell made no such blanket withdrawal of the display claims in this case. Further, Honeywell has also charged Sandel with infringement of the display patents in another lawsuit. As such, this court affirms the district court's decision to retain jurisdiction over the withdrawn claims of the '060 and '009 patents. Honeywell does not appeal the substance of the trial court's decision on the invalidity of those claims. Accordingly, this court affirms that decision.

V

On cross-appeal, Sandel and Universal appeal the district court's denial of defendants' remaining counterclaims of invalidity under 35 U.S.C. § 102(b). The Patent Act entitles an inventor "to a patent unless . . . the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." Id. The district court held a seven-day bench trial on Sandel's and Universal's counterclaims of invalidity based on these bars. The district court determined that the claims were not invalid for either a public use or a commercial sale.

Following a bench trial, this court reviews the district court's conclusions of law without deference and its findings of fact for clear error. Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1369 (Fed. Cir. 2005). The same standards apply

to review of "on sale" or "public use" determinations. Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1349-50 (Fed. Cir. 2004).

A. On-sale Bar

The on-sale bar prohibits the patenting of an invention that has been the subject of an offer for sale before critical date in § 102(b). Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 66-67 (1998). In applying the statutory on-sale bar, this court follows the test set forth in Pfaff. 525 U.S. at 67. The Pfaff test requires that (1) the invention be the subject of a commercial sale or offer for sale and (2) the invention be "ready for patenting" at the time of the offer or sale. Id. An accused infringer may overcome a patent's presumption of validity by presenting clear and convincing evidence that the patented device was on-sale before the critical date. A defendant must prove that both prongs of the test occurred before the critical date.

In this case, Universal and Sandel point to Honeywell's proposals to Gulfstream and Canadair to develop its systems with their luxury airplane. Negotiations associated with that proposal occurred between January and July of 1994.

Honeywell negotiated with Gulfstream and Canadair to apply the new system in luxury airplanes. As the district court found, "both projects involved experimental aircraft, uncertified equipment . . . ." Final Decision, 343 F. Supp. 2d at 295. Moreover, the record shows that Honeywell entered into these negotiations to facilitate its programs to test its new system with human pilots in a genuine cockpit setting. These human factor and cockpit integration tests were a part of Honeywell's program to determine that the invention worked for its intended purpose. If, and only if, these tests were successful, Honeywell proposed commercial terms for the supply of 100 new

systems to replace the GPWS systems. If the tests were not successful, Honeywell proposed to supply its GPWS systems instead. Beyond these experimental programs, Honeywell did not offer its inventive system to any other customer until well after the critical date. The record also shows, often in the form of internal corporate communications, that Honeywell did not refer to the new system as ready for sale. Thus, the record consistently shows that Honeywell's negotiations and proposals before the critical date evinced a purpose of experimentation, as the district court found. See TP Labs, Inc. v. Prof'l Positioners, Inc., 724 F.2d 965 (Fed. Cir. 1984).

Although the experimentation did not alter any specific part of Honeywell's claimed system, this aspect of the record does not prejudice Honeywell's invocation of experimentation to negate any on-sale bar. Although such evidence would strengthen the case for negating experimentation, this negating doctrine does not require changes to the claimed invention to substantiate an experimental use. See City of Elizabeth v. Am. Nicholson Pave Co., 97 U.S. 126, 135 (1877).

Regarding the second prong of the Pfaff test, the record also shows that the invention was not "ready for patenting" before the critical date. An invention is "ready for patenting" when evidence shows that the invention was reduced to practice or described in a written description sufficient to permit one of ordinary skill in the art to practice the invention without undue experimentation. Pfaff, 525 U.S. at 67-68. An invention is reduced to practice when the patentee has an embodiment that meets every limitation and operates for its intended purpose. Eaton v. Evans, 204 F.3d 1094, 1097 (Fed. Cir. 2000). An invention works for its intended purpose when there is a

demonstration of the workability or utility of the claimed invention. Fujikawa v. Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1996).

The record in this case features a videotape of the invention in use aboard an actual airplane. This video shows that the invention in operation before the critical date, which in this case is July 31, 2004. In addition, other documents and demonstrations, such as Hans Muller's Design Notes and an article published by a reporter in June, 2004, (the "George article") allegedly support a reduction to practice. Reduction to practice requires proof that the invention worked for its intended purpose. EZ Dock v. Schafer Sys., Inc., 276 F.3d 1347, 1351 (Fed. Cir. 2002). The video, according to the record and the findings of the district court, shows that Honeywell performed tests to determine that the invention worked for its intended purpose. These tests, however, were part of the Honeywell effort to reduce the invention to practice, rather than an actual reduction. Following these tests, Honeywell still had work to do to ascertain the success of the operation. Further, the documents show that the system was still in development at the time of the tests and the other documentation. In sum, Honeywell used computer simulations, test aircraft, and demonstrations to those with expertise in air safety such as pilots to move the invention toward a reduction to practice. These tests began slightly before and continued well after the critical date. The district court, after a seven-day bench trial, determined that the evidence did not clearly and convincingly show that Honeywell had reduced the invention to practice before the critical date. Further, the district court determined that the documents, including the Design Notes, did not sufficiently enable one skilled in the art to practice the invention.

Thus, the record supports the district court's findings and conclusions after trial. As such, this court affirms the district court's decision.

B. Public Use

Universal and Sandel also argue on appeal that Honeywell's claims are invalid under § 102(b) based on public use. Specifically, Universal and Sandel argue that Honeywell's flight demonstrations had a commercial purpose. The district court disagreed: "Although these flights allowed contact with potential customers, there is no evidence that they were solely or primarily for marketing purposes." Final Decision, 288 F. Supp. 2d at 308. Further, Universal and Sandel argue that one of these flights, in which a reporter was aboard, constituted a public disclosure. This reporter published an article, the George article, about this flight in which he indicated the system was still under development. Thus the district court determined that "[t]he George article clearly indicates that the system is in its development phase." Id. at 287.

The § 102(b) bar prohibits a public use of an invention more than one year before the filing date of the patent application. A barring public use requires a public use more than one year before the patent filing date that employs a completed invention in public, without confidentiality restrictions, and without permitted experimentation. Allied Colloids Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995). As noted, an experimental purpose can negate a purportedly public use. Pfaff, 535 U.S. at 66-68. "This court has repeatedly stressed that evidence of experimental use . . . operates to negate application of section 102(b)." EZ Dock, 276 F.3d at 1351-52. In explaining the difference between "experimental" use and "commercial" or "public use," the Supreme Court noted that "a bona fide effort to bring [the] invention to perfection, or to ascertain

whether it will answer the purpose intended" does not constitute a "public use." City of Elizabeth, 97 U.S. at 137. "Any attempt to use [the invention] for a profit, and not by way of experiment . . . would deprive the inventor of his right to a patent." Id.

Based on City of Elizabeth, this court has consistently distinguished permitted experimental uses from barred public or commercial uses. EZ Dock, 276 F.3d at 1352; Allied Colloids Inc., 64 F.3d at 1574. Thus, the focus of the test is whether the use was truly experimental or in fact commercial. Allied Colloids, 64 F.3d at 1576-77. Applying these negating principles to this case shows that from 1993 through the critical date, Honeywell demonstrated a version of its look ahead system to aviation-industry people through a series of in-flight demonstrations aboard its King Air airplane using a laptop computer prototype. One of these demonstrations, in March of 1994, involved the pilot and writer, Fred George (author of the George article).

These demonstrations, as the district court correctly found, were experimental and not barring public uses. Although these demonstrations did not always relate to claimed features, this court permits testing to determine the workability of an invention even if the claims do not expressly set forth the intended use under examination. EZ Dock, 276 F.3d at 1353. All of the demonstrations involved testing Honeywell's EGPWS system on flights, the intended use of the invention. In any event, because, as set forth above, this court agreed with the district court that the claimed invention was not ready for patenting prior to the critical date, this court sustains as well the trial court's finding that the presentations, including the presentation which included Fred George, are not a bar under § 102(b).

VII

Sandel appeals the district court's determination that Honeywell had not committed inequitable conduct in its procurement of its patents relating to its EGPWS system. Sandel's inequitable conduct claim arises from Honeywell's alleged failure to disclose the Gulfstream documentation or the George article. Honeywell submitted declarations from two individuals, a Mr. Daly and a Mr. Torget. Mr. Daly was Vice President and General Manager of the Flight Safety Systems Division during the relevant time period and Mr. Torget was a mechanic for the King Air aircraft. Mr. Daly filed his declaration in support of the '080 patent application. In it, he noted that regulatory approval required prior commercial use. In addition, his statement discloses the flight demonstrations and the use of the system on the Gulfstream flight. Mr. Torget was the mechanic for the King Air aircraft and responsible for maintaining the documentation necessary on the aircraft to obtain FAA authorization. He too submitted his declaration as part of the prosecution of the '080 patent. In it, he states that the activities were experiments to satisfy applicable FAA regulations.

Thus, the district court, after hearing evidence from both sides, concluded that Honeywell had made affirmative disclosures of the Gulfstream and Collins proposals and the King Air aircraft flight, which was one of the flights which resulted in the George article, to the United States Patent and Trademark Office (Patent Office). Further, the district court did not find any intent on the part of Honeywell to deceive the Patent Office. Thus, the district court concluded: "In light of the information disclosed to the examiner, Sandel and Universal have not shown that any material misstatement or

omission by Honeywell during the prosecution of the patents in suit [evinces] an intent to deceive." Final Decision, 343 F. Supp. 2d at 312.

Applicants for patents have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); see also 37 C.F.R. § 1.56. A breach of this duty—including affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information—coupled with an intent to deceive, constitutes inequitable conduct. See Molins, 48 F.3d at 1178. In determining whether inequitable conduct occurred, a trial court must determine whether the party asserting the inequitable conduct defense has shown by clear and convincing evidence that the alleged nondisclosure or misrepresentation occurred, that the nondisclosure or misrepresentation was material, and that the patent applicant acted with the intent to deceive the United States Patent and Trademark Office. Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1048 (Fed. Cir. 1995). The nondisclosure or misrepresentation must meet threshold levels of both materiality and intent. Molins, 48 F.3d at 1178. Once the threshold levels of materiality and intent have been established, the trial court must weigh materiality and intent to determine whether the equities warrant a conclusion that inequitable conduct occurred. Id. The more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find inequitable conduct. N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153, (Fed. Cir. 1987). This court reviews all of these underlying factual determinations for clear error. Glaxo, 52 F.3d at 1028.

On appeal, Sandel challenges the district court's determination that the Gulfstream documentation and George article were not material. Information is material "if there is a 'substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.' " Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991) (quoting 37 C.F.R. § 1.56 (1989)). Information cumulative of other information already before the Patent Office is not material. Here, as the district court found, Honeywell provided the Patent Office with express statements about its commercial flights and about the industry demonstrations. Final Decision, 343 F. Supp. 2d at 313. Moreover, Sandel does not challenge the district court's determination that Honeywell had no intent to deceive the Patent Office regarding its pre critical date activates. As such, this court affirms the district court's decision denying inequitable conduct.

VIII

Finally, Universal appeals the district court's decision regarding its commercial counterclaims. At the district court, Universal alleged that Honeywell "filed the lawsuit against it in bad faith with knowledge that its patents were invalid under § 102(b) and unenforceable due to inequitable conduct, as part of an overall scheme to monopolize the market and for the purpose of interfering with Universal's actual and prospective business relations." Universal asserted that Honeywell "employed negative publicity and filed the litigation against it to disrupt its business relations with potential customers." In other words, Universal charged that Honeywell's litigation was a sham.

The district court, applying the standard set forth in Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 56 (1993), determined

that "while summary judgment of non-infringement and anticipation was ultimately grounded, a reasonable litigant could have expected success on the merits of Honeywell's claim for patent infringement against those parties." Final Decision, 343 F. Supp. 2d at 326. Further, the district court determined that Universal had not shown that Honeywell used the litigation as an anti-competitive weapon. Id. After all, the record showed that Honeywell conducted a reasonable pre-suit investigation. Id. Moreover, with regard to Honeywell's publicity, the trial court correctly noted that "patentees are permitted to make representations about their rights even though they are inaccurate." Id. Because Universal did not show by clear and convincing evidence that Honeywell acted in bad faith, the district court denied Universal's counterclaims. Id.

The Supreme Court, in Professional Real Estate, 508 U.S. at 50, outlined a two-part definition of sham litigation: Only if the litigation is shown to be objectively meritless may a court proceed to examine the litigant's subjective motivation to ascertain if the litigation merely masks illegal behavior. If the litigation is not objectively baseless, it cannot be deemed a sham regardless of the subjective intent involved in bringing the litigation. "[A]n objectively reasonable effort to litigate cannot be sham regardless of subjective intent." Professional Real Estate, 508 U.S. at 57.

"We must approach a federal antitrust claim as would a court of appeals in the circuit of the district court whose judgment we review." Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875 (Fed. Cir. 1985); U.S. Philips Corp. v. Windmere Corp., 861 F.2d 695, 702 (Fed. Cir. 1988). However, questions about whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws

is decided on Federal Circuit law. Nobelpharma AB v. Implant Innovation, Inc., 141 F.3d 1059, 1067 (Fed. Cir. 1998).

Universal has not identified any evidence of record that shows a genuine case that Honeywell's infringement action was "so baseless that no reasonable litigant could realistically expect to secure favorable relief." Professional Real Estate, 508 U.S. at 673. This court agrees with the district court that Universal's assertions are without merit. Accordingly, this court holds that the district court did not err in denying Universal's commercial counterclaims.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, VACATED-IN-PART, and REMANDED.